



DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1305

[Docket No. DEA-662]

RIN 1117-AB61

Clarification Regarding the Supplier's DEA Registration Number on the Single-Sheet

DEA Form 222

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Direct final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is issuing this direct final rule to amend DEA regulations to clarify that either the purchaser or the supplier may enter a supplier's DEA registration number on the Single-Sheet DEA Form 222.

DATES: This direct final rule is effective on [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] without further action, unless significant adverse comment is received by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. If the Drug Enforcement Administration (DEA) receives significant adverse comment, it will publish a withdrawal of the rule in the Federal Register by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-662" on all correspondence, including any attachments.

Electronic comments: DEA encourages that all comments be submitted through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

Paper comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DPW, 8701 Morrisette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Telephone: (571) 776-2265.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at <http://www.regulations.gov>. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly

available, you must include the phrase “PERSONAL IDENTIFYING INFORMATION” in the first paragraph of your comment. You must also place all of the personal identifying information you do not want publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase “Confidential Business Information” in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to <http://www.regulations.gov> may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this direct final rule is available at <http://www.regulations.gov> under FDMS Docket ID: DEA-2020-0036.

Legal Authority and Background

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances; maintenance and submission of records and reports; and for the efficient execution of his statutory functions.¹ The CSA further authorizes the Attorney General to promulgate rules and regulations relating to the

¹ 21 U.S.C. 821, 827, 871(b).

registration and control of importers and exporters of controlled substances.² The Attorney General has delegated this authority to the Administrator of DEA.³

The DEA Form 222 is used by DEA registrants to order schedule I and II controlled substances. In September 2019, DEA issued a final rule to implement a new single-sheet DEA Form 222 (single-sheet form) to replace the three-part carbon copy form (triplicate form), and allowed a transition period for use of existing stocks of the triplicate form until October 30, 2021 (or earlier if the registrant exhausts its supply).⁴ Both the single-sheet and triplicate forms require certain information to be completed pertaining to the supplier (i.e., supplier name, address, and DEA registration number). The final rule set forth a procedure for the supplier filling DEA Forms 222 and providing its DEA registration number, among other things, and specifically provides that “[a] supplier may fill the order . . . and must record on the original DEA Form 222 its DEA registration number.”⁵

As previously noted, both the single-sheet and triplicate forms require the supplier’s DEA registration number to be recorded. On the triplicate form, the field for the supplier’s DEA registration number is located within a section titled “TO BE FILLED IN BY SUPPLIER.” However, on the single-sheet form, the field for the supplier’s DEA registration number is located directly above a section titled “TO BE FILLED IN BY PURCHASER.” This has led to some confusion regarding who must record the supplier’s DEA registration number on the single-sheet DEA Form 222.

Clarification on Completing the Supplier’s DEA Registration Number Information

Since the publication of the single-sheet final rule, DEA has received inquiries regarding whether the purchaser or the supplier should enter the supplier’s DEA registration number on the single-sheet form. DEA is amending its regulations to clarify that either the

² 21 U.S.C. 958(f).

³ 28 CFR 0.100(b).

⁴ New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222) 84 FR 51368, Sept. 30, 2019.

⁵ 21 CFR 1305.13(b).

purchaser or the supplier may fill in this information. DEA also notes that the single-sheet form has been slightly modified – and approved by the Office of Management and Budget (OMB) in July 2020 – by the addition of a line that separates the field for the supplier’s DEA registration number from the field titled, “PART 2: TO BE FILLED IN BY PURCHASER,” in which the supplier’s business name and address are recorded. This revised version of the form is being provided to any registrant requesting paper DEA Forms 222 pursuant to 21 CFR 1305.11.

Regulatory Analyses

Administrative Procedure Act

An agency may find good cause to exempt a rule from prior public notice provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)(B)), if it is determined to be unnecessary, impracticable, or contrary to the public interest. This rule clarifies that either the purchaser or supplier may enter the supplier’s DEA registration number on the single-sheet DEA Form 222. Furthermore, DEA notes that this rule does not impose any new requirements as the supplier’s DEA registration number is already required to be entered on the single-sheet form.⁶ Therefore, DEA concludes it is unnecessary to issue this rule for public notice and comment, prior to issuing a final rule, and finds good cause to exempt this rule from the provisions of the APA under 5 U.S.C. 553(b)(B). For the same reasons, DEA has determined that this rule is suitable for direct final rulemaking. Although DEA does not expect to receive significant adverse comment on this rule, DEA has decided to allow for public comment. If DEA receives significant adverse comment within 30 days of the publication of this final rule, it will publish a timely withdrawal of the rule in the Federal Register.

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review))

⁶ 21 CFR 1305.13(b).

This direct final rule was developed in accordance with the principles of Executive Orders (E.O.) 12866 and 13563. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. OMB's Office of Information and Regulatory Affairs (OIRA) has determined that this direct final rule is not a significant regulatory action as defined by E.O. 12866, section 3(f).

Analysis of Benefits and Costs

DEA has analyzed the economic impact of this direct final rule and estimates the annual cost to be \$0. This rule is minor and technical in nature, merely clarifying existing DEA regulations and requirements. Current regulations require the supplier's DEA registration number to be entered on the single-sheet DEA Form 222. Thus, this rule does not impose any new requirement and there is no new cost or labor burden associated with this rule.

While this direct final rule will result in no economic impact on registrants or DEA, DEA believes there are certain benefits of this rule. This rule is expected to enhance clarity as well as flexibility, by clearly stating that either the purchaser or the supplier may enter the supplier's DEA registration number on the DEA Form 222. While DEA does not have a basis to quantify the benefits, DEA believes the benefits are real and welcomed by the affected registrants.

Executive Order 12988, Civil Justice Reform

This direct final rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988 to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This direct final rule does not have federalism implications warranting the application of E.O. 13132. The direct final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This direct final rule does not have tribal implications warranting the application of E.O. 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA or other laws. As explained above, DEA determined that there is good cause to exempt this direct final rule from notice and comment. Consequently, the RFA does not apply to this direct final rule.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, DEA has determined that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under UMRA of 1995.

Paperwork Reduction Act of 1995

This direct final rule does not impose a new collection requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). This direct final rule does not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. Although the direct final rule is applicable to an existing collection of information, the rule merely clarifies certain recordkeeping requirements that already apply to registrants using DEA Form 222 and therefore does not impose any new collection of information requirement. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Congressional Review Act

OIRA has determined that this direct final rule is not a major rule as defined by Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA), 5 U.S.C. 804(2). This direct final rule will not result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based companies to compete with foreign-based companies in domestic and export markets. However, pursuant to the CRA, DEA is submitting a copy of this direct final rule to both Houses of Congress and to the Comptroller General.

List of Subjects

21 CFR Part 1305

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, DEA amends 21 CFR part 1305 as follows:

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

1. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

2. In § 1305.12, add a sentence to the end of paragraph (c) to read as follows:

§ 1305.12 Procedure for executing DEA Forms 222.

* * * * *

(c) * * * The supplier's DEA registration number may be entered by the purchaser or the supplier.

* * * * *

3. In § 1305.13, revise the first sentence of paragraph (b) to read as follows:

§ 1305.13 Procedure for filling DEA Forms 222.

* * * * *

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original DEA Form 222 its DEA registration number (if not previously entered by the purchaser) and the number of commercial or bulk containers furnished on each item and the date on which containers are shipped to the purchaser. * * *

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Anne Milgram,
Administrator

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